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Committee of Experts on the Transport of Dangerous Goods and on the Globally Harmonized System of Classification and Labelling of Chemicals

Sub-Committee of Experts on the Globally Harmonized System of Classification and Labelling of Chemicals

Thirty-fifth session
Geneva, 4-6 July 2018
Item 4 (a) of the provisional agenda
Hazard communication: labelling of small packagings

Labelling of sets or kits

Transmitted by the European Chemical Industry Council (CEFIC) on behalf of the informal correspondence group*

Introduction

1. At its thirty-fourth session, the Sub-Committee noted that the informal correspondence group had considered proposals to further improve the examples for sets or kits and that a revised proposal would be submitted to the thirty fifth session. The proposal in this document takes account of all comments received.

Proposal

2. Add a new example "Labelling of sets or kits" in annex 7 of the GHS as set out hereafter.

* In accordance with the programme of work of the Sub-Committee for 2017–2018 approved by the Committee at its eighth session (see ST/SG/AC.10/C.3/100, paragraph 98 and ST/SG/AC.10/44, paragraph 14).

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"Example 10: Labelling of - sets or kits

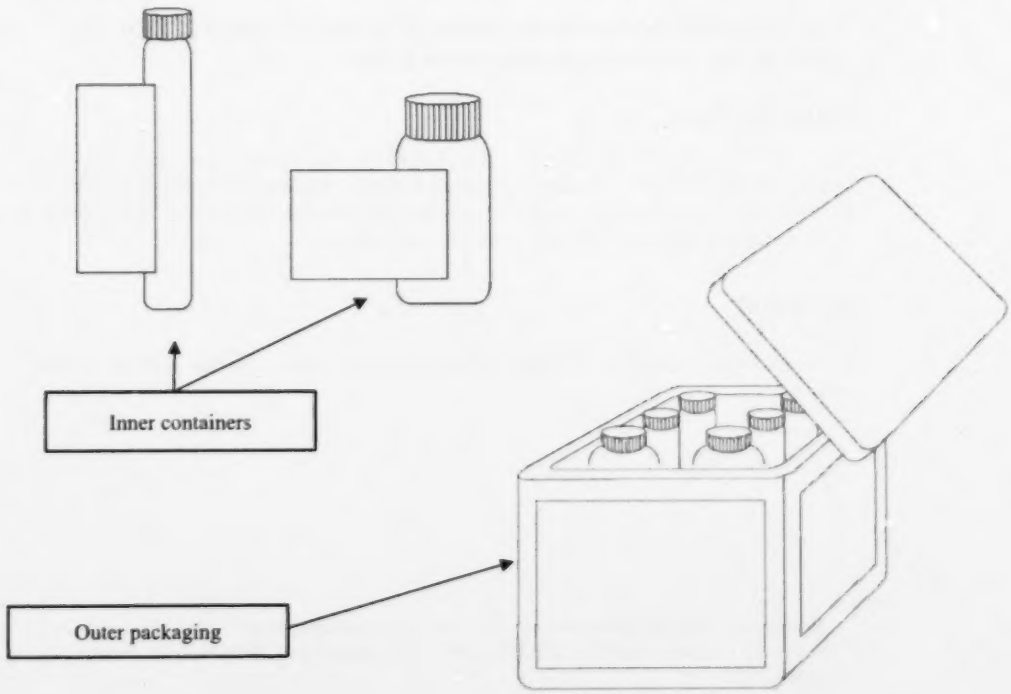
A set or kit is a combination packaging intended for defined applications. Generally a set or kit contains two or more small removable inner containers. Each inner container contains different products which can be hazardous or not hazardous substances or mixtures.

This example illustrates ways to label sets or kits where the manufacturer/supplier or competent authority has determined there is insufficient space to place together on each inner container within the kit, the GHS pictogram(s), signal word and hazard statement(s) in accordance with 1.4.10.5.4.1. This may occur when, for example, the inner containers are small, or there are a large number of hazard statements assigned to the chemical, or the information needs to be presented in multiple languages, so all the information cannot be printed on the label in a size that is easily legible. Two different scenarios where this may arise are illustrated, together with ways to provide the necessary GHS information.

Scenario A

The set or kit comprises an outer packaging containing the following inner containers: four cuvettes, each filled with the same substance or mixture (reagent 1) and two larger containers each filled with another substance or mixture (reagent 2).

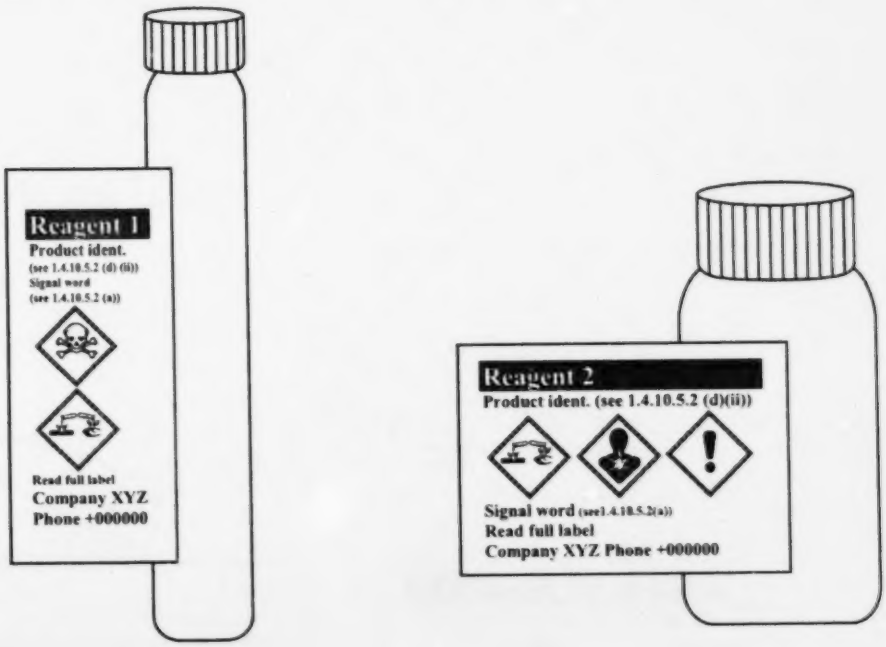
The approach is to provide minimum information on each of the inner containers containing hazardous substances or mixtures, and to provide the full GHS label information for each hazardous substance or mixture on the outer packaging. For clarity, the full label information for each hazardous substance or mixture is grouped together on the outer packaging.



Inner container label

As the area available for a label on the inner containers is not sufficient to include all the required GHS label elements, the following minimum information is included on the label of each hazardous substance or mixture:

- Product identifier[1], and an identifier for each substance or mixture matching the identifier used on the outer packaging label and SDS for that substance or mixture, e.g., "Reagent 1" and "Reagent 2"
- Pictogram(s)
- Signal word
- The statement "Read full label"
- Supplier identification (i.e. name and telephone number)



Outer packaging label

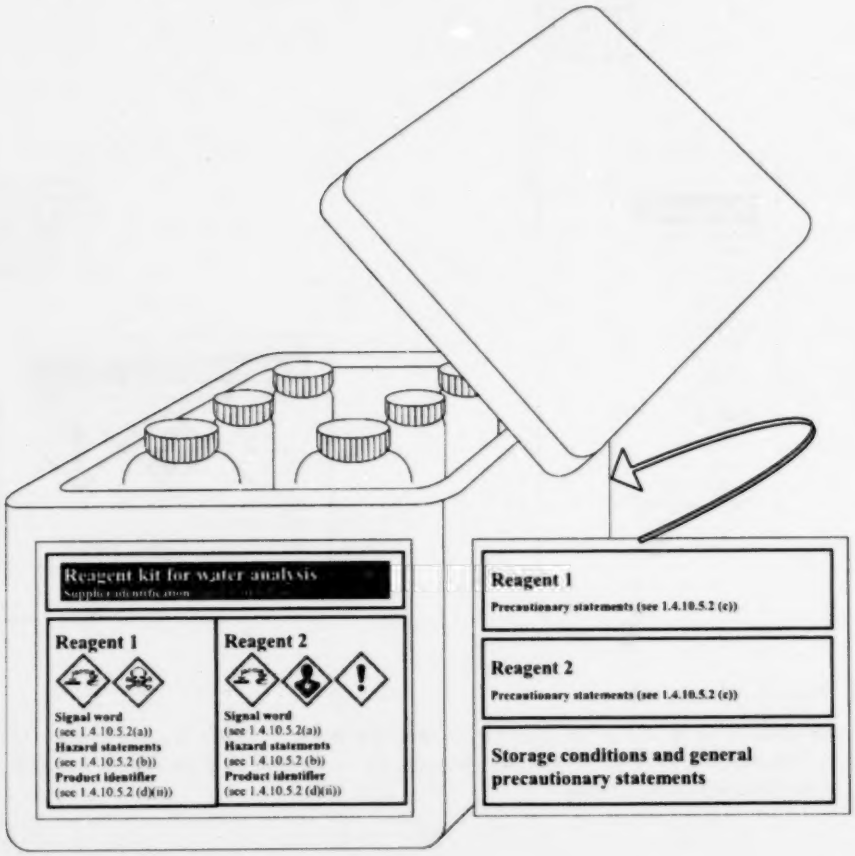
In addition to the set or kit identifier, in this case Reagent Kit for water analysis (see below), all the required GHS label elements appear on the outer packaging for each hazardous substance or mixture.

[1] Where hazardous components are required on the label, they are displayed in the appropriate languages on the outer packaging label.

The label elements for each substance or mixture on the outer packaging are grouped together in order to distinguish clearly which label elements are assigned to which substance or mixture.

However, the supplier identification need appear only once on the outer packaging. Where possible any supplemental information may also be included on the outer packaging.

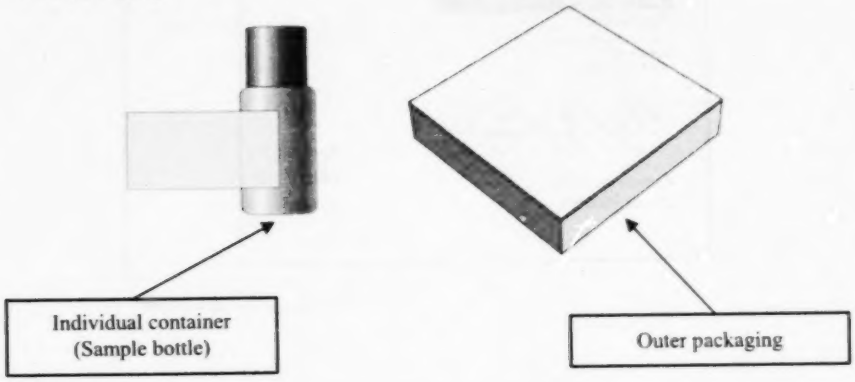
When a large number of precautionary statements are required, the precautionary statements may be located separately from the rest of the label elements, though general precautionary statements (Table A3.2.1) and precautionary statements for storage need only appear once (see also A3.3.2 in Annex 3 on flexibility in the use of precautionary statements to avoid inappropriate statements, taking into account the nature of the user (e.g. consumers, employers and workers) the quantities supplied, and the intended and foreseeable circumstances of use. In these circumstances, the precautionary statements for each substance or mixture should be grouped together on the same side of the outer packaging and on a surface that is visible under normal conditions of use.



Scenario B

This scenario addresses the situation where it is not possible to affix all appropriate GHS labelling elements for each hazardous substance or mixture in the kit directly on the outer packaging label (due to technical reasons such as the size and shape of this packaging).

This scenario presents a sample kit used for marketing purposes which consist of a large number of different substances or mixtures in individual containers (sample bottles) presented in an outer packaging (e.g. a box). Depending upon the contents of each bottle, some or all of the different substances or mixtures may be classified as hazardous. The individual inner containers (e.g. bottles) are stored in the outer packaging throughout the lifecycle of the sample kit. Customers may select individual bottles and remove them from the box to check clarity, colour or odour and then replace them into the open slot within the outer packaging.

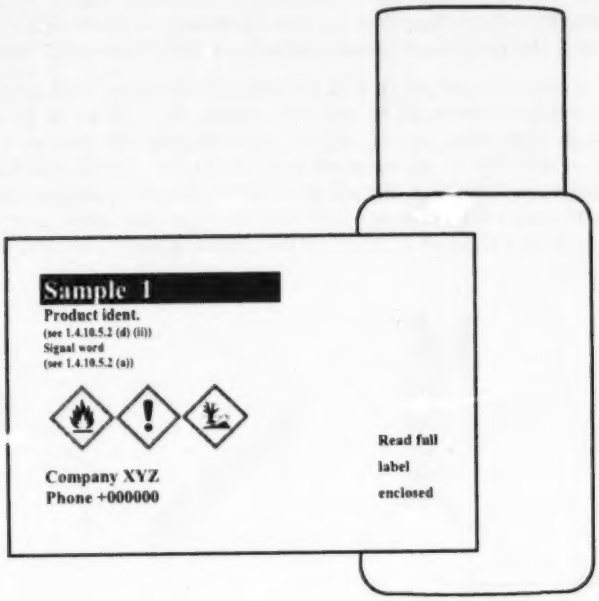


Individual container label

As the area available for a label on the different individual containers is not sufficient to include all required GHS label elements, the following minimum required information should be required:

- supplier identification (i.e. name and telephone number)
- product identifier[1]
- pictogram(s)
- signal word
- the statement "Read full label enclosed"

[1] Where hazardous components are required to be identified on the label they are displayed in the appropriate languages as part of the full label information attached to the inside of the kit.



Example of individual container label

Full label information

Attached to the inside of the outer packaging is the full GHS label information for each individual container containing a hazardous substance or mixture. The individual product identifiers on the label align with the product identifier on the individual container label. An example of the content of the full label information is shown below.

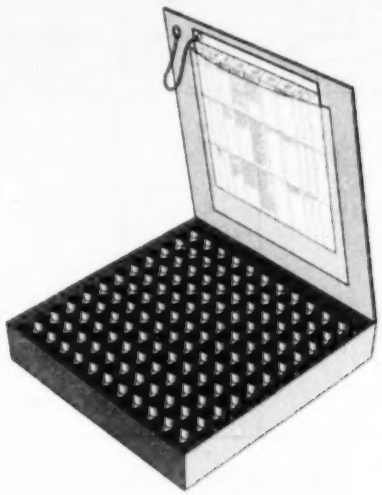
Product identifier (see 1.4.10.5.2 (d) (ii))	Pictogram(s) (see 1.4.10.4)	Signal word (see 1.4.10.5.2 (a))	Hazard statement(s) (see 1.4.10.5.2 (b))	Precautionary statement(s) (see 1.4.10.5.2 (c))	Supplemental information (see 1.4.10.5.4.2)
123		Warning	Flammable liquid and vapour. Causes skin irritation. Toxic to aquatic life with long lasting effects.	Keep away from heat, hot surfaces,sparks,open flames and other ignition sources. No smoking. Keep container tightly closed. Use explosion-proof equipment. Use non-sparking tools. Take action to prevent static discharge. Avoid release to the	

Product identifier (see 1.4.10.5.2 (d) (ii))	Pictogram(s) (see 1.4.10.4)	Signal word (see 1.4.10.5.2 (a))	Hazard statement(s) (see 1.4.10.5.2 (b))	Precautionary statement(s) (see 1.4.10.5.2 (c))	Supplemental information (see 1.4.10.5.4.2)
				environment. Wear protective gloves. IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water. In case of fire: Use dry sand, dry chemical or alcohol-resistant foam for extinction. Store in a well-ventilated place. Keep cool.	

Although the contents of each inner container may not be classified as hazardous according to the GHS, and thus would not need to be identified, it may be identified with a statement such as "Not meeting classification criteria" or "Not classified as hazardous" so as to eliminate confusion on the part of the user if the contents of an inner container is omitted from the full label information.

The document containing the full GHS label information should be organized and printed in a format that allows the user to readily identify the information for each individual container. The visibility of the label elements should be ensured without the aid of any device other than corrective lenses. The approach of this scenario may become infeasible if, given the number of samples, required languages, and precautionary statements, the document grows so large it becomes difficult to locate quickly the label information for a particular inner container.

As shown to the right, full label information regarding each inner container is contained within the outer packaging.
The sheets of full label information are permanently connected to the inside of the combination packaging using a secure method of attachment (e.g. fold out label adhered to box tie or tag as shown)



Outer packaging label

The outer box, given the limited area for labelling, will display:

- kit identifier (name of kit)
- supplier identification (see 1.4.10.5.2(e))
- storage and general precautionary statements for the kit as a whole
- pictograms for each single hazardous substance or mixture, without duplication
- signal word (the most stringent assigned to any component)
- the statement "Read full label enclosed".

MARKET KIT

Product ident. (see 1.4.10.5.2 (d) (ii))

Signal word (see 1.4.10.5.2 (a))

Precautionary Storage Statements (see 1.4.10.5.2 (c))

Read full label enclosed

Supplier identification (see 1.4.10.5.2 (e))

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Sub-Committee of Experts on the Transport of Dangerous Goods

Fifty-third session
Geneva, 25 June-4 July 2018
Item 10 (e) of the provisional agenda
Issues relating to the Globally Harmonized System of Classification and Labelling of Chemicals: Joint work with the GHS Sub-Committee

Sub-Committee of Experts on the Globally Harmonized System of Classification and Labelling of Chemicals

Thirty-fifth session
Geneva, 4-6 July 2018
Item 2 of the provisional agenda
Joint work with the Sub-Committee of Experts on the Transport of Dangerous Goods (TDG Sub-Committee)

Aerosols – Consequential amendments from proposals in ST/SG/AC.10/C.3/2018/5 - ST/SG/AC.10/C.4/2018/3 and ST/SG/AC.10/C.4/2018/9

Submitted by the European Aerosol Federation (FEA)*

1. As follow-up to the thirty-fourth session of the Sub-Committee, the European Chemical Industry Council (CEFIC) and the European Industrial Gases Associated (EIGA) submitted document ST/SG/AC.10/C.3/2018/5 - ST/SG/AC.10/C.4/2018/3 - "Proposal to classify chemicals under pressure within Chapter 2.3 of the GHS". This document proposes that aerosols and chemicals under pressure be combined and addressed in the same chapter (2.3) of the GHS, which currently addresses aerosols only. The document announces that amendments to the existing text on aerosols will be the subject of a separate proposal.

2. As follow-up to the thirty-fourth session of the Sub-Committee, Canada, jointly with the European Aerosol Federation (FEA), submitted document ST/SG/AC.10/C.4/2018/9 "Proposed amendments to chapter 2.3 to convert decision logics into text language". The proposed amendments to chapter 2.3 present the criteria for aerosols in text language.

3. This working document present the consequential amendments to the GHS, related to aerosols, if both above proposals are adopted.

4. The Sub-Committees are invited to consider and agree on these amendments.

* In accordance with the programme of work of the Sub-Committee for 2017–2018 approved by the Committee at its eighth session (see ST/SG/AC.10/C.3/100, para. 98, and ST/SG/AC.10/44, para. 14).

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Annex

Proposed consequential amendments to the GHS

1. Amend new section 2.3.1 in Chapter 2.3 as follows (Additions are underlined, deletions are in strikethrough):

"**2.3.1 Aerosols**

2.3.1.1 Definition

Aerosols, this means aerosol dispensers, are any non-refillable receptacles made of metal, glass or plastics and containing a gas compressed, liquefied or dissolved under pressure, with or without a liquid, paste or powder, and fitted with a release device allowing the contents to be ejected as solid or liquid particles in suspension in a gas, as a foam, paste or powder or in a liquid state or in a gaseous state.

2.3.1.2 Classification criteria

2.3.1.2.1 Aerosols are classified in one of the three categories of this hazard class, according to Table 2.3.1, depending on:

- their flammable properties, and
- their heat of combustion,
- if applicable, test results from the ignition distance test, the enclosed space ignition test and the aerosol foam flammability test, performed in accordance with sub-sections 31.4, 31.5 and 31.6 of the *UN Recommendations on the Transport of Dangerous Goods, Manual of Tests and Criteria*.

They should be considered for classification in Category 1 or 2 if they contain more than 1% components (by mass) which are classified as flammable according to the GHS criteria, i.e.:

- Flammable gases (see Chapter 2.2);
- Flammable liquids (see Chapter 2.6);
- Flammable solids (see Chapter 2.7);

or if their heat of combustion is at least 20 kJ/g.

Table 2.3.1: Criteria for aerosols

Category	Criteria
1	Any aerosol that contains at least 85% flammable components (by mass) and has a heat of combustion of at least 30 kJ/g; or Any aerosol that dispenses a spray that, in the ignition distance test, has an ignition distance of at least 75 cm; or Any aerosol that dispenses a foam that, in the foam flammability test, has (a) a flame height of at least 20 cm and a flame

Category	Criteria
	duration of at least 2 s, or (b) a flame height of at least 4 cm and a flame duration of at least 7 s
2	Any aerosol that dispenses a spray that does not meet the criteria for Category 1 in the ignition distance test which has (a) a heat of combustion of at least 20 kJ/g, or (b) a heat of combustion of less than 20 kJ/g along with an ignition distance of at least 15 cm, or (c) a heat of combustion of less than 20 kJ/g and an ignition distance of less than 15 cm along with either, in the enclosed space ignition test, (i) a time equivalent of 300 s/m^3 or less, or (ii) a deflagration density of 300 g/m^3 or less; or Any aerosol that dispenses a foam that does not meet the criteria for Category 1 in the foam test which has a flame height of at least 4 cm and a flame duration of at least 2 s.
	Any aerosol that contains 1% or less flammable components (by mass) and that has a heat of combustion below 20 kJ/g; or Any aerosol that contains more than 1% (by mass) flammable components or which has a heat of combustion of at least 20 kJ/g but which does not meet the criteria for Categories 1 and 2 in the ignition distance test, the enclosed space ignition test or the aerosol foam flammability test as applicable.

NOTE 1: *Flammable components do not cover pyrophoric, self-heating or water-reactive substances and mixtures because such components are never used as aerosol contents.*

NOTE 2: *Aerosols do not fall additionally within the scope of chapters 2.2 (flammable gases), 2.3.2 (chemicals under pressure), 2.5 (gases under pressure), 2.6 (flammable liquids) and 2.7 (flammable solids). Depending on their contents, aerosols may however fall within the scope of other hazard classes, including their labelling elements.*

~~2.3.2.2 An aerosol is classified in one of the three categories for this Class on the basis of its components, of its chemical heat of combustion and, if applicable, of the results of the foam test (for foam aerosols) and of the ignition distance test and enclosed space test (for spray aerosols). See decision logic in 2.3.4.1. Aerosols which do not meet the criteria for inclusion in Category 1 or Category 2 (extremely flammable or flammable aerosols) should be classified in Category 3 (non-flammable aerosols).~~

NOTE 3: *Aerosols containing more than 1% flammable components or with a heat of combustion of at least 20 kJ/g, which are not submitted to the flammability classification procedures in this chapter should be classified as aerosols, Category 1.*

2.3.1.3 Hazard communication

General and specific considerations concerning labelling requirements are provided in *Hazard communication: Labelling* (Chapter 1.4). Annex 1 contains summary tables about classification and labelling. Annex 3 contains examples of precautionary statements and pictograms which can be used where allowed by the competent authority.

Table 2.3.~~4~~2: Label elements for aerosols

	Category 1	Category 2	Category 3
Symbol	Flame	Flame	*No symbol*
Signal word	Danger	Warning	Warning
Hazard statement	Extremely flammable aerosol Pressurized container: May burst if heated	Flammable aerosol Pressurized container: May burst if heated	Pressurized container: May burst if heated

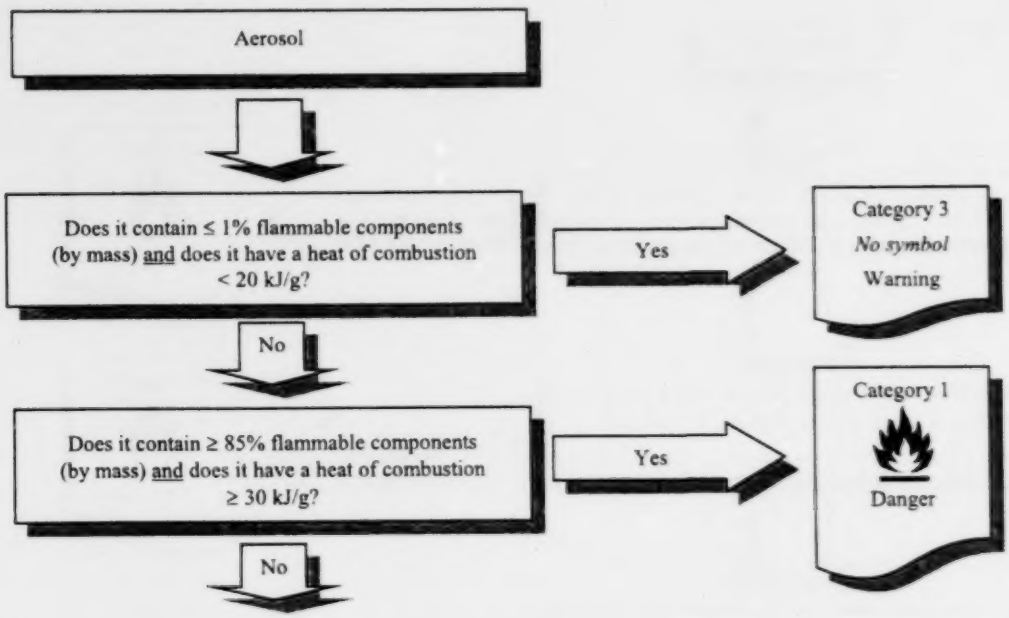
2.3.1.4 Decision logic ~~and guidance~~

The decision logic ~~and guidance~~, which follows, ~~are not part of the harmonized classification system, but have~~ has been provided here as additional guidance. It is strongly recommended that the person responsible for classification studies the criteria before and during use of the decision logic.

2.3.1.4.1 *Decision logic*

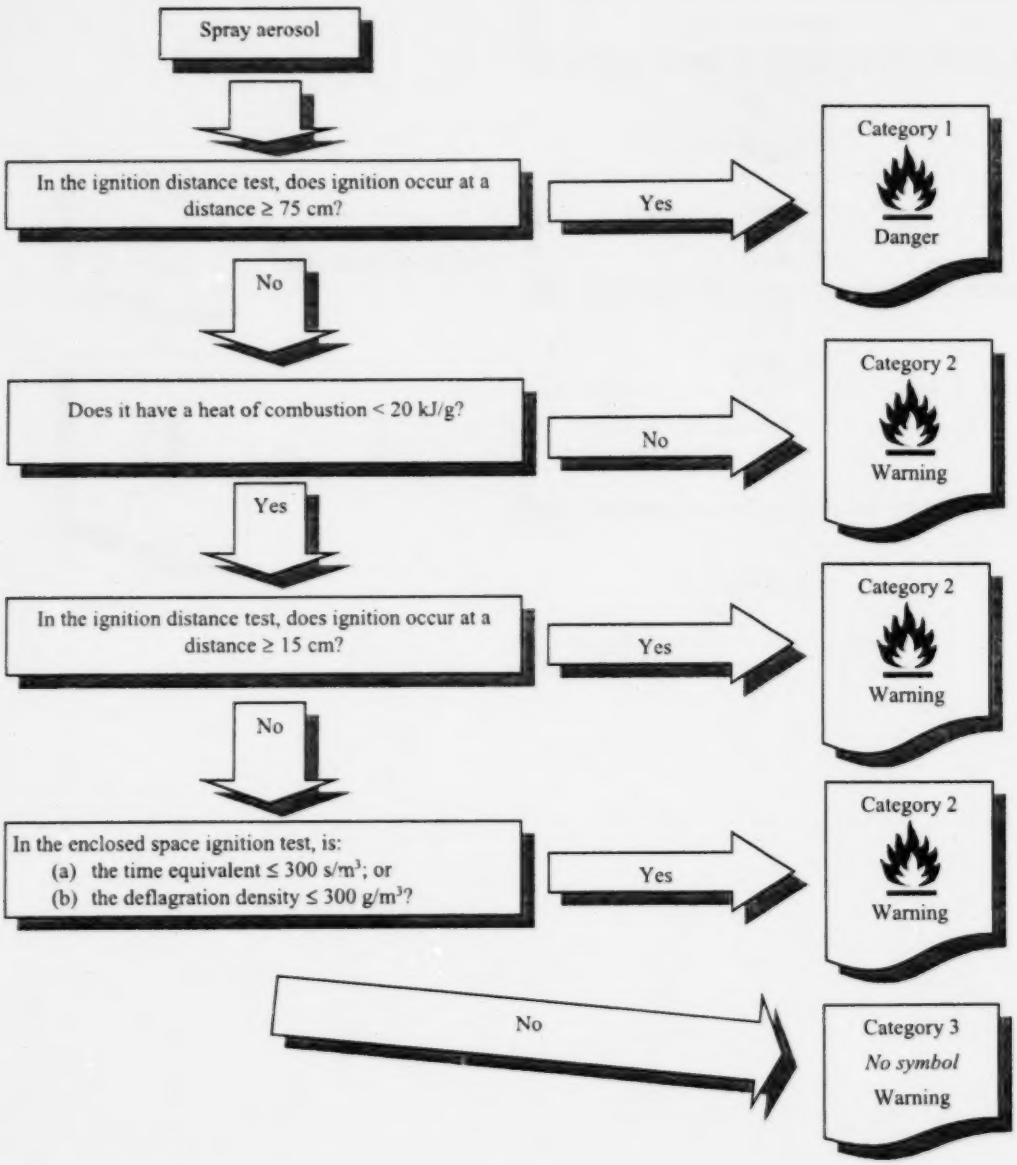
To classify an aerosol data on its flammable components, on its chemical heat of combustion and, if applicable, the results ~~of the foam test (for foam aerosols) and~~ of the ignition distance test and enclosed space test (for spray aerosols) and of the foam test (for foam aerosols) are required. Classification should be made according to decision logics 2.3.1 (a) to 2.3.1 (c).

Decision logic 2.3.1 (a) for aerosols

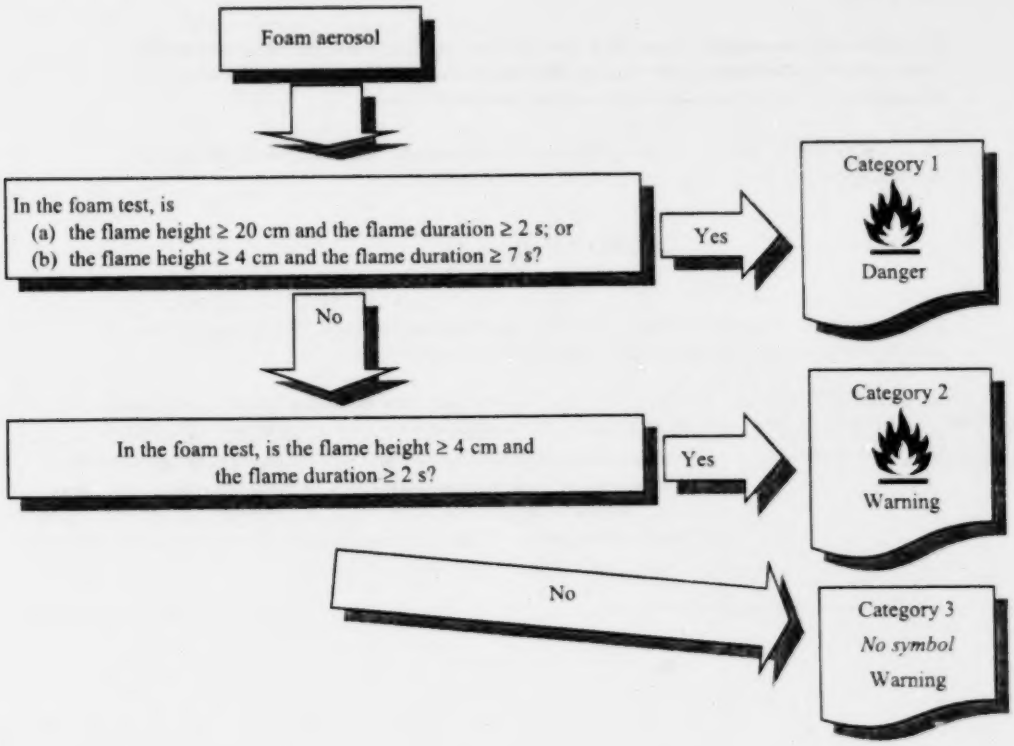

Aerosol
Does it contain ≤ 1% flammable components (by mass) and does it have a heat of combustion < 20 kJ/g?
Yes
Category 3
No symbol
Warning
No
Does it contain ≥ 85% flammable components (by mass) and does it have a heat of combustion ≥ 30 kJ/g?
Yes
Category 1
Danger
No

For spray aerosols, go to decision logic 2.3.1 (b);
For foam aerosols, go to decision logic 2.3.1 (c);

Decision logic 2.3.1 (b) for spray aerosols



Decision logic 2.3.1 (c) for foam aerosols


Foam aerosol
In the foam test, is
(a) the flame height ≥ 20 cm and the flame duration ≥ 2 s; or
(b) the flame height ≥ 4 cm and the flame duration ≥ 7 s?
Yes
Category 1
Danger
No
In the foam test, is the flame height ≥ 4 cm and the flame duration ≥ 2 s?
Yes
Category 2
Warning
No
Category 3
No symbol
Warning

~~**2.3.4.2 *Guidance***~~

~~2.3.4.2.1 The chemical heat of combustion (Δhc), in kilojoules per gram (kJ/g) is the product of the theoretical heat of combustion (Δh_{comb}) and the combustion efficiency, usually less than 1.0 (a typical efficiency is 0.95 or 95%).~~

~~For a composite formulation, the chemical heat of combustion is the summation of the weighted heats of combustion for the individual components, as follows:~~

$$\Delta hc(product) = \sum_{i}^{n} [w_i\% \times \Delta hc_i]$$

~~where:~~

~~Δhc = chemical heat of combustion (kJ/g);~~
~~$w_i\%$ = mass fraction of component i in the product;~~
~~Δhc_i = specific heat of combustion (kJ/g) of component i in the product;~~

~~The chemical heat of combustion can be found in the literature, calculated or determined by tests (see ASTM D 240, ISO/FDIS 13943:1999 (E/F) 86.1 to 86.3 and NFPA 30B).~~

~~2.3.4.2.2 See sub-sections 31.4, 31.5 and 31.6 of the *UN Recommendations on the Transport of Dangerous Goods, Manual of Tests and Criteria*, for Ignition distance test, Enclosed space ignition test, and Aerosol foam flammability test.~~

2. In Annex 3, Section 3, amend the *Matrix of precautionary statements by hazard class/category applicable to aerosols under A3.3.5* as follows:

"AEROSOLS
(Chapter 2.3, section 2.3.1)"

3. In Annex 4, amend the entry applicable to aerosols in Table A4.3.9.2 (*Data relevant with regard to physical hazard classes (supplemental)*) as follows:

Chapter	Hazard Class	Property/Safety characteristic/ Test result and Remarks/Guidance
2.3; section 2.3.1	Aerosols	– indicate the total percentage (by mass) of flammable components unless the Aerosol is classified as Aerosol cat.1 because it contains more than 1% flammable components or has a heat of combustion of at least 20 kJ/g and is not submitted to the flammability classification procedures (see the Note 3 in Chapter 2.3, paragraph 2.3.1.2.~~1~~1)

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Sub-Committee of Experts on the Globally Harmonized System of Classification and Labelling of Chemicals

Thirty-fifth session

Geneva, 4-6 July 2018
Item 3 (h) of the provisional agenda
Classification criteria and related hazard communication: other issues

Amendment of the guidance on calculating specific heats of combustion for composite formulations in Chapter 2.3

Transmitted by the expert from Sweden*

Background

1. GHS Chapter 2.3 on Aerosols contains guidance on how to calculate the specific heat of combustion for a "composite formulation", see section 2.3.4.2 of that chapter. While the essence of equation is correct the way it is cast may lead to confusion and miscalculations, which may in turn lead to misclassifications.

2. There is a proposal from CEFIC and EIGA to amend Chapter 2.3 in order to include chemicals under pressure, see ST/SG/AC.10/C.4/2018/3. That document contains the corresponding guidance in its section 2.3.3. The expert from Sweden proposes that the guidance section is amended to provide mathematical consistency of the equation and logical flow of the surrounding text.

* In accordance with the programme of work of the Sub-Committee for 2017–2018 approved by the Committee at its eighth session (see ST/SG/AC.10/C.3/100, para. 98 and ST/SG/AC.10/44, para. 14).

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Discussion

3. The main problem with the current equation is the use of the symbol "w_i%" to denote a fraction. A fraction is a number between zero and one, not to be confused with a percentage which is one hundred times the fraction. The symbol "w_i%" is thus misleading in relation to what is actually meant, which is a fraction.

4. There is also inconsistent use of "specific heat of combustion" (an entity expressed in kJ/gram) versus "heat of combustion" (an entity expressed in kJ/mole), which may cause confusion. And for clarity it may be better to use brackets instead of subscripts to denote dependency on the variable *i*, since a subscript already appears in the denotation of the specific heat of combustion (Δh_c). Furthermore, the introduction that explains the difference between a practical and a theoretical combustion seems rather to be an explanatory comment to the calculation procedure, and therefore would probably fit better after the calculation procedure has been introduced.

Proposal

5. The expert from Sweden proposes the section to be cast as follows (text to be deleted in bold strike-through, new text in bold underline, note that equation denotations are proposed to be changed accordingly although for clarity have not been underlined):

2.3.3 ***Guidance on specific heat of combustion***

~~**The specific heat of combustion (Δh_c), in kilojoules per gram (kJ/g) is the product of the theoretical heat of combustion (ΔH_c) and the combustion efficiency, usually less than 1.0 (a typical efficiency is 0.95).**~~

For a composite formulation, the specific heat of combustion **of the product** is the summation of the weighted **specific** heats of combustion for the individual components, as follows:

$$\Delta h_c(\text{product}) = \sum_{i}^{n} [w(i) \times \Delta h_c(i)]$$

Where:

Δh_c(product) = specific heat of combustion (kJ/g) **of the product**;

Δh_c(i) = specific heat of combustion (kJ/g) of component i in the product;

w(i) = mass fraction of component i in the product;

n = **total number of components in the product**

The specific heats of combustion**, which are given in kilojoules per gram (kJ/g),** can be found in the scientific literature, calculated or determined by tests (see ASTM D 240, NFPA 30B.). **Note that experimentally measured heats of combustion usually differ from the corresponding theoretical heats of combustion, since the combustion efficiency normally is less than 100% (a typical combustion efficiency is 95%).**

6. For clarity, the section as proposed would read:

"**2.3.3** ***Guidance on specific heat of combustion***

For a composite formulation, the specific heat of combustion of the product is the summation of the weighted specific heats of combustion for the individual components, as follows:

$$\Delta h_c(\text{product}) = \sum_{i}^{n} [w(i) \times \Delta h_c(i)]$$

Where:

Δh_c(product) = specific heat of combustion (kJ/g) of the product;

$\Delta h_c(i)$ = specific heat of combustion (kJ/g) of component i in the product;

w(i) = mass fraction of component i in the product;

n = total number of components in the product

The specific heats of combustion, which are given in kilojoules per gram (kJ/g), can be found in the scientific literature, calculated or determined by tests (see ASTM D 240, NFPA 30B.). Note that experimentally measured heats of combustion usually differ from the corresponding theoretical heats of combustion, since the combustion efficiency normally is less than 100% (a typical combustion efficiency is 95%).".

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Sub-Committee of Experts on the Globally Harmonized System of Classification and Labelling of Chemicals

Thirty-fifth session

Geneva, 4-6 July 2018
Item 4 (b) of the provisional agenda
Hazard communication:
Improvement of annexes 1 to 3 and further rationalization of precautionary statements

Proposed changes to Annex 3 of the GHS to improve medical response precautionary statements (P310 to P315)

Transmitted by the expert from the United Kingdom on behalf of the informal working group on improving annexes 1, 2 and 3 of the GHS*

Background

1. In line with its mandate for the 2017-2018 biennium the informal working group has taken forward work under its Workstream 1: "to develop proposals to rationalise and improve the comprehensibility of hazard and precautionary statements for users, while taking into account usability for labelling practitioners. This may include proposals to rationalise and clarify ambiguous or unhelpful instructional precautionary statements (PS), such as statements relating to medical response and disposal."

2. This document presents the outcome of work on item 1 in the Group's workplan (UN/SCEGHS/32/INF.12/Rev.1) where the issue is summarised as: "The precise meaning of the medical response statements (P310-P315) is not clear and manufacturers/suppliers

* In accordance with the programme of work of the Sub-Committee for 2017–2018 approved by the Committee at its eighth session (see ST/SG/AC.10/C.3/100, para. 98 and ST/SG/AC.10/44, para. 14).

have encountered difficulties in choosing the appropriate wording from the two options. Translation of the Precautionary Statement and conditions for use has also resulted in discrepancies.".

3. Specific issues arising from the existing medical response PS include:

- There are too many;
- Providing options using a forward slash "/" or three dots "…" has not been successful, as often no choice is made and these notations appear on labels;
- Access to poison centres (where they exist) varies in different jurisdictions. In some jurisdictions access is restricted to medical staff only whilst in others they are also available to the general public;
- Although "medical advice" and "medical attention" can be distinguished[1], in practice the distinction is subtle and not always helpful in providing clear messages for medical response in the event of an incident. Furthermore, translation of these terms into other languages can be problematic[2].

Discussion

Medical response precautionary statements

4. In undertaking its work on medical response statements, the informal working group decided to start with a blank sheet and adopted the following general principles:

- Keep it simple;
- Look at a simple matrix of urgency versus seriousness, and consider possible medical response for the four possible combinations of high and low (High High (HH); High Low (HL); Low High (LH); and Low Low (LL));
- Focus high urgency/high seriousness (HH) response on situations where immediate medical help is needed (acute high hazard), i.e. potentially life-threatening situations;
- To keep it simple, use the same medical response statement for hazard classes/categories within the three other quadrants (HL, LH and LL) if possible;
- Consider the following qualifiers for low urgency situations, where approporiate: **if you feel unwell**, or **if exposed or concerned**;
- Avoid choices or additions for suppliers by not using '/' or '…' (c.f. Poison Centre/doctor/…), where possible;
- Aim for simple, succinct, translatable and universally understood PS, applicable in all jurisdictions that distinguish the hazard classes and categories requiring immediate/urgent medical help from those requiring less urgent medical help.

5. Figure 1 below brings together the informal working group's considerations for the new medical response PS and the proposed allocation of the hazard classes and categories.

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[1] Informal document INF.13 (thirty-second session) – "Medical advice and medical attention".

[2] Document ST/SG/AC.10/C.4/2016/20 – "Precautionary statements on medical advice/attention: correction of linguistic discrepancies".

6. The Sub-Committee may wish to note that work to ensure correct allocation of hazard sub-categories in Annexes 1, 2 and 3 is addressed in a separate working document (ST/SG/SC.10/C.4/2018/6). The notation in this paper on medical response PS is based on GHS revision 7.

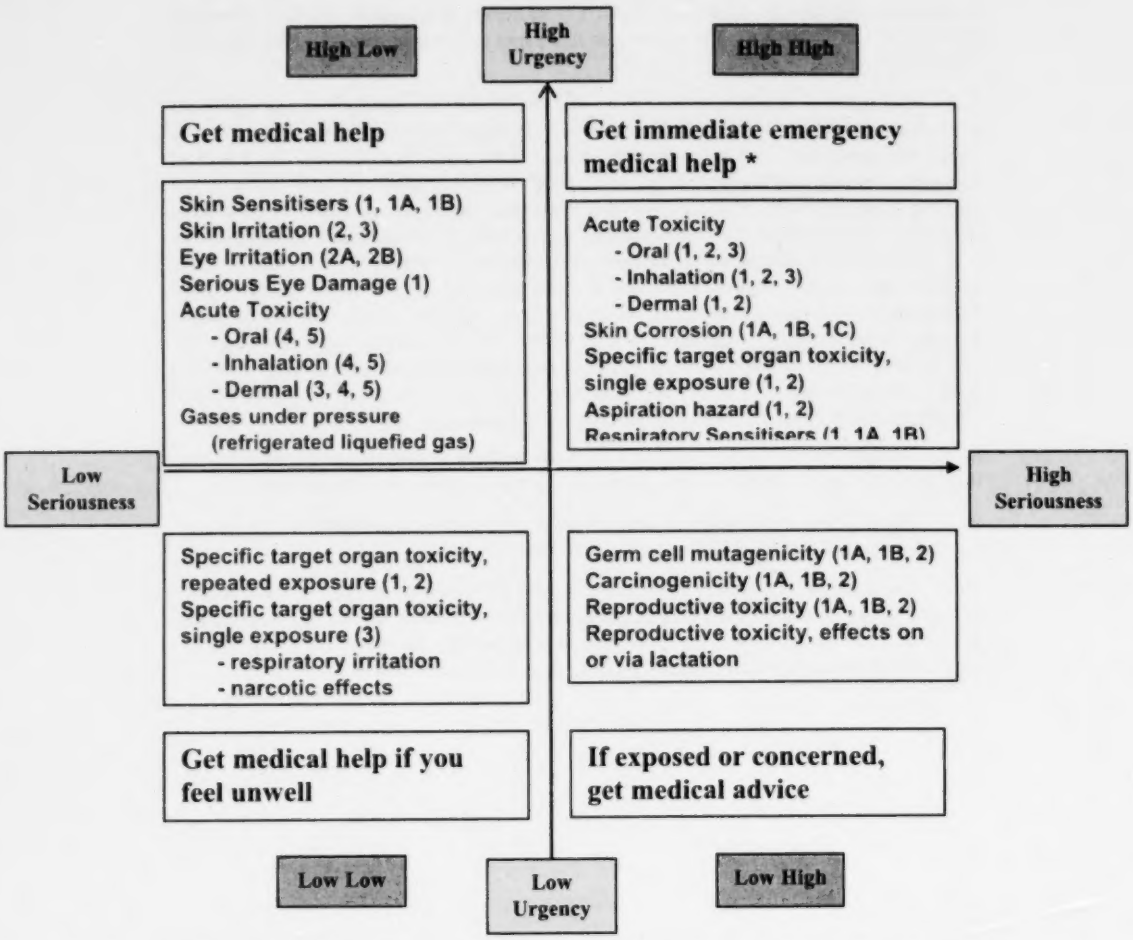
7. The informal working group agreed that the PS for the chemicals in hazard classes and categories allocated in the HH quadrant, i.e. potentially life-threatening, should clearly signal the need for emergency medical help. For many jurisdictions the PS "**Get immediate emergency medical help**" will be sufficient. A challenge was to find a way to indicate more precisely what to do in the emergency situation where this is considered necessary. Noting that in the past providing options using a forward slash "/" or three dots "…" has not been successful in the context of medical response, the informal working group proposes a new approach in Column 5 to permit the use of additional information. This enables the competent authority or manufacturer / supplier to add 'Call', followed by the appropriate emergency telephone number for the country or region concerned (e.g. 911, 111 or 999), or by the appropriate provider of emergency medical help, which could be a poison centre, emergency centre, doctor or alternative, in line with the arrangements and organisation of the health services in the country or region concerned.

8. To help ensure that the emergency response services worldwide are focussed where they are most needed, this additional information is applicable to the HH quadrant only.

9. The informal working group is not aware of any significant problems in translating the four proposed PS for medical response into other languages.

10. Consistent with the current approach, the new PS would always follow the relevant **IF…** PS (P301-P306), sometimes in conjunction with one or more specific actions. Some examples of possible combination statements with the new PS for medical response that suppliers could use in practice are in Part I of informal document INF.8.

Figure 1


High Low
High Urgency
High High
Get medical help
Skin Sensitisers (1, 1A, 1B)
Skin Irritation (2, 3)
Eye Irritation (2A, 2B)
Serious Eye Damage (1)
Acute Toxicity
- Oral (4, 5)
- Inhalation (4, 5)
- Dermal (3, 4, 5)
Gases under pressure
(refrigerated liquefied gas)
Get immediate emergency medical help *
Acute Toxicity
- Oral (1, 2, 3)
- Inhalation (1, 2, 3)
- Dermal (1, 2)
Skin Corrosion (1A, 1B, 1C)
Specific target organ toxicity, single exposure (1, 2)
Aspiration hazard (1, 2)
Low Seriousness
High Seriousness
Specific target organ toxicity, repeated exposure (1, 2)
Specific target organ toxicity, single exposure (3)
- respiratory irritation
- narcotic effects
Germ cell mutagenicity (1A, 1B, 2)
Carcinogenicity (1A, 1B, 2)
Reproductive toxicity (1A, 1B, 2)
Reproductive toxicity, effects on or via lactation
Get medical help if you feel unwell
If exposed or concerned, get medical advice
Low Low
Low Urgency
Low High

* Competent Authority or manufacturer / supplier may add "Call" followed by the appropriate emergency telephone number, or the appropriate emergency medical help provider, for example, a poison centre, emergency centre or doctor.

11. The proposed new PS with the hazard classes/categories to which they are assigned are also shown in Table 1 below. The advantages of the proposed PS compared to the existing P310 to P315 are:

(a) The number of medical response PS is reduced from 6 to 4.

(b) The action to take is conveyed more clearly and the potential confusion between 'medical advice' and medical attention' is avoided.

(c) The new PS don't use "/" or "…" and so manufacturers and suppliers don't have to make difficult choices between options.

Where immediate medical help is needed provision has been made to allow competent authorities or manufacturers / suppliers to add additional information specifying the appropriate number to call or the emergency provider to contact.

12. In considering the new medical response PS the informal working group agreed that in the event of accidental exposure to substances and mixtures classified as gases under pressure (refrigerated liquefied gas) or serious eye damage the situation would not generally be potentially life-threatening, and the appropriate response was **"Get medical help"** rather than **"Get immediate emergency medical help"**.

Presentation of the new medical response precautionary statements

13. In line with advice from the secretariat, to avoid confusion between the existing medical response PS (P310 to P315) in versions of the GHS up to and including the seventh revised edition, it is proposed to delete the current codes P310 to P315 and assign new codes P316 to P319 to the four proposed new medical response PS. For clarity "deleted" is inserted into column 1 of Table A3.2.3 beneath the codes that become obsolete. In addition, some explanatory text is inserted in Annex 3, section 2 (see Part II of informal document INF.8).

Further changes and rationalisation of precautionary statements

14. In the proposed new PS for medical response the existing P308, "**If exposed or concerned:"** is incorporated in P318 "**If exposed or concerned get medical advice**" in a similar way to "… **if you feel unwell"** (now part of P314). The proposed new PS P318 is applied to the hazard classes carcinogenic, mutagenic and reprotoxic (CMRs) in line with P308 now. However, P308 is also currently applied to substances or mixtures classified as specific target organ toxicity, single exposure (STOT SE) (1, 2). The informal working group considered that in these cases "**Get immediate emergency medical help"** is the appropriate medical response. As the routes of exposure for classification as STOT SE (1, 2) are often not known or available, P308 is retained for this hazard class and categories. However, P308+P313, which applies only to CMRs, can be deleted.

15. P308 is also needed to retain the existing provision to replace three or more routes of exposure (P301 to 306) in combination with the same medical response statement with **"IF exposed or concerned:"**.

16. P302 and P303 are also rationalised by deleting P303, "**IF ON SKIN (or hair)**", and using instead P302, "**IF ON SKIN"**. The hazard classes and categories currently allocated to P303 (Flammable liquids (1 - 3) and Skin corrosion (1A, 1B, 1C)) are added to P302. It was considered that skin includes hair, and the distinction between P302 and P303 is not meaningful or helpful in practice.

Proposal

17. Table 1 below sets out the proposed new PS for medical response.

18. Other changes in the proposal are to:

(a) Make the conforming changes in Table A3.2.3 to combination PS including medical response to reflect Table 1;

(b) Delete the response precautionary statements, hazard classes, hazard categories and associated column 5 entries for the following PS from Table A3.2.3,

and insert "**deleted**" in column 1 below each of the codes: P303, P310, P311, P312, P313, P314, P315;

(c) Delete the following combined PS entry from Table A3.2.3: P308 + P313;

(d) Delete the hazard classes / categories for carcinogenic, mutagenic and reprotoxic (CMRs) as listed under P308 in Table A3.2.3;

(e) Move the hazard classes / categories for flammable liquids (1, 2, 3) and skin corrosion (1A, 1B, 1C) as listed under P303 to P302 in Table A3.2.3, and delete P303;

(f) Make the conforming changes to combination PS including P30;

(g) Amend A3.2.3.5 of Annex 3, section 2 to cover provision of additional information as appropriate (new text underlined):

"A3.2.3.5 In cases where additional information is required, or information either has to be or may be specified, this is indicated by a relevant entry in column (5) in plain text."

(h) Insert a new paragraph A.3.2.3.9 in Annex 3, Section 2 on deleted codes:

"A3.2.3.9 Where precautionary statements become obsolete, "**deleted**" is inserted under the existing code in column 1 of the tables in this Section to avoid potential confusion between codes used in different editions of the GHS."

(i) Replace A3.3.2.4 in Annex 3, Section 3, "Application of precautionary statements concerning medical response" with the corresponding text in Part II of informal document INF.8;

(j) Make the necessary conforming amendments to the matrix of PS by hazard class/category in Annex 3, Section 3.

19. Part II of informal document INF.8 sets outs the changes in full. New text is shown in red. Deleted text is shown in ~~strikethrough~~.

Action requested

20. The Sub-Committee is invited to agree to the proposed changes to Annex 3, sections 2 and 3 as set out in paragraphs 17 to 18 above and Part II of informal document INF.8.

Table 1

Code (1)	Response precautionary statements (2)	Hazard class (3)	Hazard category (4)	Conditions for use (5)
P316	**Get immediate emergency medical help.**	Acute toxicity, oral (chapter 3.1)	1, 2, 3	Competent Authority or manufacturer / supplier may add, 'Call' followed by the appropriate emergency telephone number, or the appropriate emergency medical help provider, for example, a Poison Centre, Emergency Centre or Doctor.
		Acute toxicity, dermal (chapter 3.1)	1, 2	
		Acute toxicity, inhalation (chapter 3.1)	1, 2, 3	
		Skin corrosion (chapter 3.2)	1A, 1B, 1C	
		Respiratory sensitization (chapter 3.4)	1, 1A, 1B	
		Specific target organ toxicity, single exposure, (chapter 3.8)	1, 2	
		Aspiration hazard (chapter 3.10)	1, 2	
P317	**Get medical help.**	Gases under pressure (chapter 2.5)	Refrigerated liquefied gas	
		Acute toxicity, oral (chapter 3.1)	4, 5	
		Acute toxicity, dermal (chapter 3.1)	3, 4, 5	
		Acute toxicity, inhalation (chapter 3.1)	4, 5	
		Skin irritation (chapter 3.2)	2, 3	
		Serious eye damage (chapter 3.3)	1	
		Eye irritation (chapter 3.3)	2A, 2B	
		Skin sensitization (chapter 3.4)	1, 1A, 1B	
P318	**If exposed or concerned, get medical advice.**	Germ cell mutagenicity (chapter 3.5)	1A, 1B, 2	
		Carcinogenicity (chapter 3.6)	1A, 1B, 2	
		Reproductive toxicity (chapter 3.7)	1A, 1B, 2	
		Reproductive toxicity, effects on or via lactation (chapter 3.7)	Additional category	
P319	**Get medical help if you feel unwell.**	Specific target organ toxicity, single exposure, respiratory tract irritation (chapter 3.8)	3	
		Specific target organ toxicity, single exposure, narcotic effects (chapter 3.8)	3	
		Specific target organ toxicity, repeated exposure (chapter 3.9)	1, 2	

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Sub-Committee of Experts on the Globally Harmonized System of Classification and Labelling of Chemicals

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Geneva, 4-6 July 2018
Item 4 (b) of the provisional agenda
Hazard communication: improvement of annexes 1 to 3 and further rationalization of precautionary statements

Proposed changes to P201 and P202

Transmitted by the expert from the United Kingdom on behalf of the working group on improving annexes 1, 2 and 3 of the GHS*

Background

1. In line with its mandate for the 2017-2018 biennium the informal working group has taken forward work under its Workstream 1: "to develop proposals to rationalise and improve the comprehensibility of hazard and precautionary statements for users, while taking into account useability for labelling practitioners."

2. This paper presents the outcome of work on item 6 in the Group's workplan (informal document INF.12/Rev.1, thirty-second session) where the issue is: "Consider merging P201 and P202 (without losing meaning)".

Discussion and proposal

3. P201, **"Obtain special instructions before use"**, and P202, **"Do not handle until all safety precautions have been read and understood"**, both aim to draw attention to the

* In accordance with the programme of work of the Sub-Committee for 2017–2018 approved by the Committee at its eighth session (see ST/SG/AC.10/C.3/100, para. 98 and ST/SG/AC.10/44, para. 14).

particular importance of safety precautions where high hazard chemicals are handled and used.

4. The hazard classes and categories where P201 and P202 apply are similar. Both apply to chemicals classified as carcinogenic, mutagenic and toxic to reproduction (CMR) (all categories). There is a condition of use for application of the CMR hazard classes/categories that P201 should be omitted where P202 is used. In addition, P201 applies to unstable explosives and P202 to chemically unstable gases A and B within the hazard class flammable gases (Table A3.2.2).

5. A footnote to Table 2.1.1 explains that "Unstable explosives are those which are thermally unstable and/or too sensitive for normal handling, transport and use. Special precautions are necessary." As they can't be transported, handling and use should only be where they are manufactured. The use of chemically unstable gases is also expected to be limited to certain industrial activities, and in some jurisdictions the use of category 1A and 1B CMR substances by the public is restricted. The implication is that the target audience for P201 and P202 is often employers/workers.

6. The existing language in both P201 and P202 is not helpful or consistent. P201 refers to obtaining special instructions before use, but not to reading/understanding these instructions and ensuring the necessary safety precautions are in place. The term "special instructions" does not appear to be used elsewhere in the GHS, and it is not immediately clear whether it refers to part of the safety data sheet, to on-site rules/operating procedures prepared by the employer, or to other instructions. On the other hand, P202 refers to reading and understanding the safety precautions, but not to applying them in practice.

7. The considerations in paragraphs 3 to 6 above point to combining the existing P201 and P202 statements to convey the message that chemicals with these particularly hazardous classifications should not be used until all the available safety information has been read and understood, and the necessary safety precautions have been put in place. The proposal, therefore, is to delete P201 and amend P202 to: **"Do not use until all available safety information is understood: follow all specified safety instructions."** The working group considered whether the second part of the phrase should be "follow all specified safety instructions and precautions". On balance their view was that there is an overlap between instructions and precautions and the shorter phrase was preferred.

8. The new combined phrase would be applied to the same hazard classes and categories as applied now to both P201 and P202. Where the new P202 is applied to consumer products, the existing condition for P103, "omit where P202 is used", ensures that only one of these precautionnary statements applies.

9. The proposed changes to combine P201 and P202, and the consequential changes elsewhere in Annex 3 are shown in informal document INF.9.

Action

10. The Sub-Committee is invited to agree the proposed changes in paragraph 7 above shown in informal document INF.9.